

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

ANTIMICROBIAL PROGRAM BRANCH

IN 04/24/90 OUT 05/05/90

Reviewed by Srinivas Gowda *WEC*
5/16/90 Date 05/05/90

EPA Reg. No. or File Symbol 34292-1

EPA Petition or EUP No. None

Date Division Received 02/07/90

Type Product (s): Preservative/Bacteriostatic/Fungistatic/
Algistatic

MRID No(s) 413911-01

Product Manager PM 31 (Lee)

Product Name Dow Corning 5700 Antimicrobial Agent

Company Name Dow Corning Corporation

Submission Purpose Amendment to add Residual self-sanitizing
activity claims against athlete's foot
fungi for impregnated socks with efficacy
data and proposed label

Type Formulation Technical Chemical for Manufacturing Use

Active Ingredient (s): 3-

(Trimethoxysilyl)propyldimethyloctadecyl ammonium chloride.42

200.0 **Introduction**

200.1 **Uses (s)**

See attached proposed label.

200.2 **Background Information**

The current submission is a proposed amendment to add residual self-sanitizing activity claims for treated socks against athlete's foot fungi, Trichophyton mentagrophytes with efficacy data and proposed label.

201.0 **Data Summary**

201.1 **Brief Description of Tests** (MRID No. 413911-01)

"Residual self-sanitizing activity test data by Richard L. Gettings, Dow Corning Corporation, 2200 W. Salzburg road, Midland, MI 48640, dated 04-10-87.

201.2 **Test Results:**

The methodology employed and test results are attached.

Conclusions: Test fabricsamples(cotton/nylon/linen/lycra, acrylic/polypropylene/nylon/lycra, wool/silk/nylon/lycra, and wool/acrylic/nylon/lycra) treated with the product (1.25% on weight of fabric) demonstrated residual self-sanitizing activity (equal to or greater than 99.9% reduction) over the parallel control after 24 hours of contact time at 37°C against Trichophyton mentagrophytes and for up to 10 laundry cycles.

SELF-SANITIZING ACTIVITY OF TREATED SOCK FABRICS AGAINST ATHLETE'S FOOT FUNGUS

PURPOSE

To demonstrate that sock fabrics, treated with Dow Corning 5700 Antimicrobial Agent/SYLGARD Treatment, are self-sanitizing against the athlete's foot fungus *Trichophyton mentagrophytes*.

TEST MATERIALS

Cotton/nylon/linen/lycra and acrylic/polypropylene/nylon/lycra sock fabrics were treated with Dow Corning 5700 Antimicrobial Agent in a commercial manufacturing process at 1.0% O.W.F. (on weight of fabric). Wool/silk/nylon/lycra and wool/acrylic/nylon/lycra were treated at 1.25% O.W.F. Untreated socks of identical fabric types were used as controls.

MICROBIOLOGICAL METHODS

Dow Corning 5700 Antimicrobial Agent treated sock fabrics and untreated sock fabrics were tested according to the attached protocol. The inoculum level (CFU/mL) was adjusted higher than 100,000 conidia/mL so as to recover approximately 1,000,000 conidia per sampling. This was done to increase the sensitivity of the test.

Lethen broth has been shown in the historical database for Dow Corning 5700 Antimicrobial Agent and other quats to be effective as a neutralizer in a test system.

The appropriate dilutions were incorporated in to the recovery phase of the test to account for possible increases in number of CFU/sample recovered.

RESULTS

The fungal counts from treated and untreated sock fabrics are presented in Table I (cotton/nylon/linen/lycra), Table II (acrylic/polypropylene/nylon/lycra), Table III (wool/silk/nylon/lycra), and Table IV (wool/acrylic/nylon/lycra).

The treated sock fabrics were self-sanitizing against the athlete's foot fungus as compared to untreated sock fabrics, through at least 10 laundering cycles. The activity diminished slowly after at least 10 launderings using the test method to determine efficacy.

TABLE I

Antifungal Activity¹ of Cotton/Nylon/Linen/Lycra Sock Fabric
Treated² with Dow Corning® 5700 Antimicrobial Agent³

Sample	Number of Launderings ⁴	Fungal CFU/Sample at:		Log Reduction ⁶	Percent Reduction ⁶
		"0" Time	24 Hours		
A	0	2.3×10^6	$<10^2$	>4.3	>99.99
B	0	1.8×10^6	$<10^2$	>4.3	>99.99
C ⁵	0	2.0×10^6	$<10^2$	>4.3	>99.99
Control	0	2.2×10^6	2.2×10^6	--	--
A	5	1.7×10^6	$<10^2$	>4.3	>99.99
B	5	2.1×10^6	1.2×10^2	4.2	99.99
C	5	1.9×10^6	$<10^2$	>4.3	>99.99
Control	5	1.9×10^6	2.1×10^6	--	--
A	10	2.5×10^6	1.6×10^3	3.1	99.9
B	10	1.8×10^6	1.1×10^3	3.3	99.9
C	10	2.1×10^6	1.8×10^3	3.0	99.9
Control	10	2.5×10^6	2.6×10^6	--	--
A	20	2.0×10^6	1.9×10^3	3.1	99.9
B	20	1.9×10^6	2.2×10^4	2.0	99.0
C	20	2.4×10^6	1.5×10^3	3.2	99.9
Control	20	3.1×10^6	3.1×10^6	--	--
A	25	2.0×10^6	1.8×10^5	1.1	91.4
B	25	2.5×10^6	8.9×10^4	1.4	95.8
C	25	1.9×10^6	7.5×10^4	1.4	95.4
Control	25	1.8×10^6	1.9×10^6	--	--

NOTES:

1. Antifungal activity against Trichophyton mentagrophytes.
2. Fabric treated at 1.0% O.W.F.
3. Equivalent to SYLGARD® Treatment.
4. Laundered with AATCC detergent and rinsed 2 times in water.
5. Sample C was a 60-day, shelf-life sample.
6. Log reduction and percent reduction were calculated for the treated samples (A,B,C) using the average "0" time counts for each set of laundering cycles.

TABLE II

Antifungal Activity¹ of Acrylic/Polypropylene/Nylon/Lycra Sock Fabric
Treated² with Dow Corning® 5700 Antimicrobial Agent³

Sample	Number of Launderings ⁴	Fungal CFU/Sample at:		Log Reduction ⁶	Percent Reduction ⁶
		"0" Time	24 Hours		
A	0	3.6×10^6	$<10^2$	>4.5	>99.99
B	0	2.8×10^6	$<10^2$	>4.5	>99.99
C ⁵	0	3.4×10^6	$<10^2$	>4.5	>99.99
Control	0	3.2×10^6	3.4×10^6	--	--
A	5	3.7×10^6	1.5×10^2	4.3	>99.99
B	5	3.9×10^6	$<10^2$	>4.5	>99.99
C	5	3.2×10^6	1.1×10^2	4.5	>99.99
Control	5	2.9×10^6	3.0×10^6	--	--
A	10	3.1×10^6	2.9×10^3	3.0	99.9
B	10	3.6×10^6	3.8×10^3	2.9	99.9
C	10	3.3×10^6	3.6×10^3	2.9	99.9
Control	10	3.9×10^6	3.7×10^6	--	--
A	20	3.1×10^6	8.4×10^3	2.6	99.7
B	20	3.0×10^6	6.8×10^3	2.7	99.8
C	20	2.8×10^6	1.2×10^4	2.4	99.6
Control	20	3.1×10^6	3.4×10^6	--	--
A	25	1.9×10^6	1.6×10^5	1.3	94.5
B	25	2.8×10^6	7.8×10^4	1.6	97.3
C	25	3.6×10^6	9.3×10^4	1.5	96.8
Control	25	3.4×10^6	3.4×10^6	--	--

NOTES:

1. Antifungal activity agent Trichophyton mentagrophytes.
2. Fabric treated at 1.0% O.W.F.
3. Equivalent to SYLGARD® Treatment.
4. Laundered with AATCC detergent and rinsed 2 times in water.
5. Sample C was a 60-day, shelf-life sample.
6. Log reduction and percent reduction were calculated for the treated samples (A,B,C) using the average "0" time counts for each set of laundering cycles.

TABLE III

Antifungal Activity¹ of Wool/Silk/Nylon/Lycra Sock Fabric
Treated² with Dow Corning® 5700 Antimicrobial Agent³

Sample	Number of Launderings ⁴	Fungal CFU/Sample at:		Log Reduction ⁶	Percent Reduction ⁶
		"0" Time	24 Hours		
A	0	1.9×10^6	$<10^2$	>4.4	>99.99
B	0	2.4×10^6	$<10^2$	>4.4	>99.99
C ⁵	0	3.1×10^6	$<10^2$	>4.4	>99.99
Control	0	2.8×10^6	3.0×10^6	--	--
A	5	2.6×10^6	1.3×10^2	4.2	99.99
B	5	1.5×10^6	1.1×10^2	4.3	99.99
C	5	1.8×10^6	1.1×10^2	4.3	99.99
Control	5	3.0×10^6	2.8×10^6	--	--
A	10	3.5×10^6	3.0×10^3	2.9	99.9
B	10	1.7×10^6	1.2×10^3	3.3	99.9
C	10	2.5×10^6	2.4×10^3	3.0	99.9
Control	10	2.8×10^6	2.9×10^6	--	--
A	20	3.0×10^6	4.5×10^3	2.7	99.8
B	20	2.3×10^6	8.9×10^3	2.5	99.6
C	20	2.4×10^6	8.5×10^3	2.5	99.6
Control	20	1.9×10^6	3.1×10^6	--	--
A	25	1.8×10^6	1.1×10^5	1.4	95.4
B	25	2.2×10^6	2.6×10^5	1.0	89.2
C	25	3.1×10^6	9.8×10^4	1.4	95.9
Control	25	2.6×10^6	3.1×10^6	--	--

NOTES:

1. Antifungal activity against Trichophyton mentagrophytes.
2. Fabric treated at 1.25% O.W.F.
3. Equivalent to SYLGARD® Treatment.
4. Laundered with AATCC detergent and rinsed 2 times in water.
5. Sample C was a 60-day, shelf-life sample.
6. Log reduction and percent reduction were calculated for the treated samples (A,B,C) using the average "0" time counts for each set of laundering cycles.

TABLE IV

Antifungal Activity¹ of Wool/Acrylic/Nylon/Lycra Sock Fabric
Treated² with Dow Corning® 5700 Antimicrobial Agent³

<u>Sample</u>	<u>Number of Launderings⁴</u>	<u>Fungal CFU/Sample at:</u>		<u>Log Reduction⁶</u>	<u>Percent Reduction⁶</u>
		<u>"0" Time</u>	<u>24 Hours</u>		
A	0	9.9×10^5	$<10^2$	>4.1	>99.99
B	0	1.4×10^6	$<10^2$	>4.1	>99.99
C ⁵	0	1.1×10^6	$<10^2$	>4.1	>99.99
Control	0	2.0×10^6	1.8×10^6	--	--
A	5	9.7×10^5	1.7×10^2	3.9	>99.9
B	5	1.4×10^6	1.4×10^2	4.0	>99.9
C	5	1.1×10^6	1.8×10^2	3.8	>99.9
Control	5	1.3×10^6	1.1×10^6	--	--
A	10	1.9×10^6	9.9×10^2	3.1	99.9
B	10	1.3×10^6	1.6×10^3	2.9	99.9
C	10	1.1×10^6	1.0×10^3	3.1	99.9
Control	10	9.9×10^5	1.2×10^6	--	--
A	20	1.0×10^6	1.1×10^4	2.2	99.3
B	20	2.1×10^6	9.8×10^3	2.2	99.4
C	20	1.7×10^6	1.3×10^4	2.1	99.2
Control	20	1.5×10^6	1.4×10^6	--	--
A	25	1.0×10^6	9.7×10^4	1.1	92.5
B	25	1.8×10^6	1.1×10^5	1.1	91.5
C	25	9.8×10^5	1.3×10^5	1.0	90.0
Control	25	1.4×10^6	1.4×10^6	--	--

NOTES:

1. Antifungal activity against Trichophyton mentagrophytes.
2. Fabric treated at 1.25% O.W.F.
3. Equivalent to SYLGARD® Treatment.
4. Laundered with AATCC detergent and rinsed 2 times in water.
5. Sample C was a 60-day, shelf-life sample.
6. Log reduction and percent reduction were calculated for the treated samples (A,B,C) using the average "0" time counts for each set of laundering cycles.